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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/751,308	01/02/2004	Richard J. Melker	10457-041	8794
29847	7590	11/23/2005		
BEUSSE BROWNLEE WOLTER MORA & MAIRE 390 N. ORANGE AVENUE SUITE 2500 ORLANDO, FL 32801			EXAMINER NATARAJAN, VIVEK	
			ART UNIT 3735	PAPER NUMBER

DATE MAILED: 11/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/751,308	MELKER ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	Vivek Natarajan	3735

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 02 January 2004.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-17 is/are pending in the application.
  - 4a) Of the above claim(s) 4 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-3 and 5-17 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 1/2/04 is/are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date: _____
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
Paper No(s)/Mail Date <u>6/15/05</u>	6) <input type="checkbox"/> Other: _____

## DETAILED ACTION

### *Election/Restrictions*

1. This application contains claims directed to the following patentably distinct species of the claimed invention:

- A. A pediatric probe 10P(as disclosed in ¶0074)
- B. An adult probe 10A(as disclosed in ¶0074)

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claims 1-3 and 6-17 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record

showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

2. During a telephone conversation with Mr. Timothy Van Dyke on 11/16/05 a provisional election was made without traverse to prosecute the invention of Species B, Claim 5. Affirmation of this election must be made by applicant in replying to this Office action. Claim 4 is withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

#### ***Claim Rejections - 35 USC § 102***

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-2 and 5-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Isaacson et al. (US Patent No. 5,800,349). Isaacson discloses a hook-shaped oximeter probe (Fig. 9) that measures light absorbence across the vascularized tissue of a patient and can readily be adapted to clip to an adult's cheek. The probe 40 comprises a frame having an inner and outer face, with a proximal arm connected at one end to a cable 56 and at the other end to a bridging section 120 connected to a distal arm. The emitter 32 is positioned under a pad 70 and contains both an infrared and red LED (col. 1, lines 26-40). The detector 36 is positioned under a second pad 72 (see Fig. 7). Both the emitter and detector are connected to a monitoring system for powering the light sources and for processing the detected signals (col. 8, lines 40-65). The probe further

comprises a boot to connect the probe frame to the cable 126 (see Fig. 10 or 11). A spring 74 (see Fig. 8) provides an elastic force that allows the probe to retain its configuration even after a transient deflection (col. 8, lines 13-33).

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Isaacson et al. as applied to Claims 1-2 above, and further in view of Rafert et al. (US Patent No. 5,817,008). Isaacson discloses the claimed probe including a first pad 70 positioned over two LEDs and a second pad 72 positioned over a detector. The pads are spread apart to conform to the thickness of the tissue to be measured, but are not dome-shaped. Rafert et al. discloses an oximeter probe (Fig. 2) with dome-shaped pads 58, 60 covering the light emitting means 30, 32 and the light detecting means 38, and teaches that rounding the pads minimizes any shearing effects when applied to a patient's skin (col. 5, lines 17-40). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the oximeter probe as disclosed by Isaacson et al. by using dome-shaped pads as taught by Rafert et al. since this allows for minimization of shearing effects at the sensor-tissue interface.

6. Claims 7-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Isaacson et al. as applied to Claims 1-2 and 6 above. Isaacson discloses a hook-shaped oximeter probe (Fig. 9) that measures light absorbence across the vascularized tissue of a patient and can readily be adapted to clip to an adult's cheek. The probe 40 comprises a frame having an inner and outer face, with a proximal arm connected at one end to a cable 56 and at the other end to a bridging section 120 connected to a distal arm. The emitter 32 is positioned under a pad 70 and contains both an infrared and red LED (col. 1, lines 26-40). The detector 36 is positioned under a second pad 72 (see Fig. 7). Both the emitter and detector are connected to a monitoring system for powering the light sources and for processing the detected signals (col. 8, lines 40-65). The probe further comprises a boot to connect the probe frame to the cable 126 (see Fig. 10 or 11). A spring 74 (see Fig. 8) provides an elastic force that allows the probe to retain its configuration even after a transient deflection (col. 8, lines 13-33). Although Isaacson does not disclose particular details as to the spring constant or probe resiliency, he indicates that the spring may be of a tension as preferred by the individual. It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to select a spring with a particular tension to impart a certain resiliency, including having the parameters as claimed by applicant, to an oximeter probe as taught by Isaacson, since this allows the probe to meet the preferred requirements of each individual.

7. Claims 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Isaacson et al. as applied to Claims 1-2 and 6 above, and further in view of Guthrie et

al. (US Patent No. 5,619,992). Isaacson discloses the claimed probe, but does not include a transparent plastic covering sleeve configured to slide over the entirety of the probe. Guthrie discloses an oximeter probe (Fig. 5) wherein a transparent covering sleeve 44 fits over the probe 20 and teaches that the sleeve protects the probe from contamination (col. 4, lines 12-25). The sleeve may be made of "a plastic film or the like" (col. 2, lines 2-4). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the oximeter probe as disclosed by Isaacson et al. by fitting it with a transparent plastic covering sleeve as taught by Guthrie et al. since this allows the probe to be protected from contamination.

8. Claims 14-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Isaacson '349, and further in view of Isaacson et al. (US Patent No. 6,190,327). Isaacson '349 discloses a hook-shaped oximeter probe (Fig. 9) that measures light absorbence across the vascularized tissue of a patient and can readily be adapted to clip to an adult's cheek. The probe 40 comprises a frame having an inner and outer face, with a proximal arm connected at one end to a cable 56 and at the other end to a bridging section 120 connected to a distal arm. The emitter 32 is positioned under a pad 70 and contains both an infrared and red LED (col. 1, lines 26-40). The detector 36 is positioned under a second pad 72 (see Fig. 7). Both the emitter and detector are connected to a monitoring system for powering the light sources and for processing the detected signals (col. 8, lines 40-65). The probe further comprises a boot to connect the probe frame to the cable 126 (see Fig. 10 or 11). The probe lastly comprises a plug means 128 for reversible and adjustable engagement with an associated device.

Isaacson '349 does not teach providing this plug means along the outer face of the proximal arm of the probe, nor does he indicate that the attached device is either a capnography sampler or cannula device. Applicant has not disclosed that providing the means for attachment on the *outer* face of the proximal arm provides any particular advantage or solves a stated problem. Isaacson '327 discloses an oximeter probe 12 with a means for attaching to a capnography sampler 14, and indicates that the aforementioned oximeter probe 12 could be any known oximeter in the art (see Fig. 1 and the description thereof in col. 3, lines 5-28), such as that disclosed by Isaacson '349. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the oximeter probe as disclosed by Isaacson '349 by attaching a capnography sampler as taught by Isaacson '327, and to provide the means for attachment along the outer face of the proximal arm of the probe as a matter of obvious design choice, since this allows for measurement of both oxygen and carbon dioxide levels.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vivek Natarajan whose telephone number is (571)272-6249. The examiner can normally be reached on Mon-Fri, 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ali Imam can be reached on (571)272-4737. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3735

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

VN



ERIC F. WINAKUR  
PRIMARY EXAMINER